

REMARKS:

Claims 1-3 and 5-20 are pending.

Claims 1, 12 and 13 were objected to for containing periods not associated with abbreviations. In response, these claims have been amended to recite, for example, "(a)" instead of "a." at the beginning of each method step. Accordingly, the objection is believed to have been obviated.

Claims 7 and 9-16 (due to their dependence from claim 7) were rejected under 35 U.S.C. 112, second paragraph, for omitting an essential structural relationship. Claim 7 has been amended to recite a vacuum source with a piston to clarify what is meant by "measurement of a piston displacement rate." Accordingly, this rejection is believed to have been obviated.

Claims 1-3 and 5-20 have been rejected under 35 U.S.C. 103(a) as being obvious in view of either U.S. 4,765,325 (hereinafter "Crutchfield") alone (claims 1-3, 5 and 17) or in combination with U.S. 3,948,589 by DuBois (claims 6 and 9), U.S. Patent Publication 2003/0100888 by Spinello (claims 7 and 9-16), or U.S. Patent Publication 2003/0172925 by Zocca et al. (claims 18-20).

Crutchfield describes a method and apparatus for determining respirator face mask fit that involves measuring mask leakage with a flow meter after a test subject exhales most of the air from his lungs, holds his breath, and the air valve (i.e., breathing port) through which the test subject breaths is closed. See Col. 8, lines 53-55. Then, a vacuum source is used to create a chosen negative pressure (Col. 8, lines 59-63).

In contrast, as described in Applicant's Specification at paragraphs [0070] - [0074] of the published Application, claim 1 is directed to a respirator fit testing method that includes the step of "activating a switch that closes a breathing port of said respirator, thereby initiating a controlled negative pressure testing protocol, when intra-respirator pressure substantially equals ambient pressure."

In other words, the method of claim 1 recites closing the breathing port during the point in time at which intra-respirator pressure substantially equals ambient pressure, while Crutchfield teaches closing the breathing port after the test subject exhales most of the air from his lungs (which generates a positive pressure inside the mask) and then creating a negative pressure.

Thus, the test method of claim 1 begins generating a controlled negative pressure only after ambient pressure conditions exist inside the mask, thereby virtually eliminating the possibility that the "challenge pressure" (the negative pressure at which mask leakage measurements take place) will be initially overshoot (e.g., due to excess inhalation by the test subject prior to the test commencing) and result in the test needing to be repeated.

Because Crutchfield does not teach or fairly suggest closing the breathing port when intra-respirator pressure substantially equals ambient pressure as recited in step (c) of claim 1, this claim cannot be rendered obvious by this reference.

Moreover, step (c) of claim 1 is not inherently disclosed by Crutchfield because exhaling prior to the breathing port being closed does not necessarily result in an ambient intra-mask pressure ("To establish inherency, the extrinsic evidence 'must make clear that the missing

descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).)

Similarly, the apparatus claim 17 includes a recitation that substantially tracks the language of claim 1 (i.e., "wherein activation of the switch closes said breathing port of said respirator and initiates a controlled negative pressure testing protocol after intra-respirator pressure substantially equals ambient pressure."). Consequently, this claim also cannot be rendered obvious by Crutchfield. Moreover, as all other claims depend from either claims 1 or 17, these claims likewise are not obvious.

In view of the foregoing, the applicant respectfully submits that the claims of the present invention are distinguishable from the cited art, and, thus, present patentable subject matter.

No fee is believed to be due with this amendment. Please charge any unforeseen costs to our Deposit Account No. 17-0055.

Respectfully submitted,

Quarles & Brady, LLP



Gavin J. Milczarek-Desai
Reg. No. 45,801

520-770-8716 Phone
520-770-2235 Fax